

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,557	07/16/2001	Takahiko Ishiguro	Q65441	6024
7590 12/19/2003 SUGHRUE MION ZINN MACPEAK & SEAS, PLLC 2100 Pennsylvania Avenue, NW Washington, DC 20037-3213			EXAMINER	
			WHISENANT, ETHAN C	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	09/904,557	ISHIGURO ET AL.			
Office Action Summary	Examiner	Art Unit			
	Ethan Whisenant, Ph.D.	1634			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
	Responsive to communication(s) filed on <u>03 September 2003</u> .				
,	action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>10-16</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>10-12</u> is/are rejected.					
7)⊠ Claim(s) <u>13-16</u> is/are objected to.					
8) Claim(s) are subject to restriction and/o	r election requirement.				
Application Papers					
9)☐ The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correct					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. §§ 119 and 120					
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of: 1.⊠ Certified copies of the priority documents have been received.					
<ul> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ul>					
* See the attached detailed Office action for a list of the certified copies not received.					
13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.					
a) The translation of the foreign language provisional application has been received.					
14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.					
Attachment(s)					
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal P	(PTO-413) Paper No(s) atent Application (PTO-152)			
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	6)  Other: .				

Application/Control Number: 09/904,557

Art Unit: 1634

## FINAL REJECTION

1. The applicant's Response (filed 02 SEP 03) to the Office Action has been entered. Following the entry of the claim amendment(s), Claim(s) 11-18 is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

## 35 USC § 102

**2.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in -

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

# Claim Rejections under 35 USC § 102

3. Claim(s) 10, 12 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. [WO99/57143 (1999)].

Please note that Jones et al. [EP1077219 (2001)] is being used as the translation of the Jones et al. [WO99/57143 (1999)] patent document. All references to column(s) and/or paragraph(s) refer to Jones et al. [EP1077219 (2001)].

Application/Control Number: 09/904,557 Page 3

Art Unit: 1634

Claim 10 is drawn to a method for determining whether a selected DNA molecule encodes a gene expression region, said method comprising 2 required steps. To begin, RNA transcripts are obtained from an organism which comprises said DNA molecule. Finally, the RNA transcripts are screened for an RNA transcripts that is complementary to said selected DNA molecule, wherein the nucleotide sequence of said selected DNA molecule is known, to thereby determine whether said selected DNA molecule encodes a gene expression region.

Jones et al. teach a method for determining whether a selected DNA molecule encodes a gene expression region comprising the two required steps recited in Claim 1. See for example the abstract and Column 19-23, paras [0072] - [0084]. Note that the selected DNA molecule is EST (W17142).

Claim 12 is drawn to an embodiment of the method of Claim 10 wherein RNA transcripts are screened via PCR wherein the PCR primers are derived from the selected DNA molecule. Jones et al. teach this limitation. See para [0073].

## 35 USC § 103

- **4.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Application/Control Number: 09/904,557 Page 4

Art Unit: 1634

### **CLAIM REJECTIONS UNDER 35 USC § 103**

**6.** Claim(s) 11 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. [WO99/57143 (1999)].

Claim(s) 11 is drawn to an embodiment of the method of Claim 10 wherein said selected DNA molecule consists of from 100-200 nucleotides.

Jones et al. teach all of the limitations of Claim 11 except these authors do not explicitly teach an embodiment wherein said selected DNA molecule consists of from 100-200 nucleotides. Note that the selected DNA molecule EST (W17142) comprises 244 nucleotides. Therefore, it can be said that Jones et al. do not teach an embodiment wherein the selected DNA molecule consists of from 100-200 nucleotides. However, it was well known at the time of the invention that the ESTS present in the databases comprise short fragments of expressed genes. Therefore, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Jones et al. wherein ESTS which consists of from 100-200 nucleotides are used as the selected DNA molecule in order to identify novel genes using the gene discovery techniques present in Jones et al.

Please note that substitution of one well known method/reagent with known properties for a second well known method/reagent with well known properties would have been *prima facie* obvious to the ordinary artisan at the time of the invention in the absence of an unexpected result. As regards the motivation to make the substitution recited above, the motivation to combine arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making this obviousness rejection comes from the M.P.E.P. at 2144.07 and 2144.09.

#### **CLAIM OBJECTIONS**

**7.** Claim(s) 13-16 is /are objected to because it/they is/are dependent upon a rejected independent base claim.

#### RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

**8.** Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are most in view of the new ground(s) of rejection.

#### CONCLUSION

9. Claim(s) 10-16 is/are rejected and/or objected to for the reason(s) set forth above.

**10.** Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

**11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

♦Please note that the USPTO is scheduled to relocate to its new home in Alexandria, VA very soon (JAN 04'). As a result, the examiner's telephone and desktop FAX numbers will be changing. The new telephone and desktop FAX numbers for Ethan Whisenant, Ph.D. are/will be as shown below:

New Telephone number: (571) 272-0754

New FAX number: (571) 273-0754.

ETHAN WHISENANT PRIMARY EXAMINER

Art Unit 1634